Amendment and Response Applicants: Shin et al.

Serial Number: 09/852,988





45. (New) The method of claim 41, wherein the step of radially compressing at least a portion of the stent comprises radially compressing the stent along its entire length.

46. (New) The method of claim 41, wherein, in the step of radially compressing at least a portion of the stent, the stent is radially compressed by forcing the stent into contact with a forming stem.

REMARKS

Claims 1 to 9 and 34 to 36 have been canceled without prejudice above. New claims 41 to 46 have been added.

Claims 10 to 33 and 41 to 46 will be pending after entry of the above amendments.

For the convenience of the Examiner, Applicants' remarks herein are set forth under appropriate subheadings.

Objections to the Specification

The specification was objected to because of inconsistent terminology on page 14. Page 14 has been amended above. A marked-up copy of page 14 and a substitute page 14 are enclosed herewith.

Accordingly, Applicants respectfully request that the objections to the specification be withdrawn.

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Claim rejections under 35 U.S.C. § 102

The Examiner rejected claims 1, 2, 3, 6 to 9, 20, 21, 24, and 34 to 36 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,725,519 (Penner et al.).

Claims 1, 2, 3, 6 to 9 and 34 to 36 have been canceled without prejudice above. Accordingly, this rejection of these claims is rendered moot.

Applicants respectfully traverse this rejection of claims 20, 21, and 24. Penner et al. teach a device in which a stent is pre-loaded within a tube. The tube passes through a bore of a proximal component, and the diameter of the tube is thus reduced. This reduces the diameter of the stent by compressive force. The result is that the stent is crimped around a balloon catheter. In other words, Penner et al. describe a particular method of "crimping" a stent on a balloon catheter. As in all crimping methods, the diameter of the stent is reduced during loading in order to secure the stent over the balloon catheter.

In contrast, the present invention, as recited in claims 20, 21, and 24, is a method of loading a stent onto a delivery catheter in a radially contracted position at the time it is mounted on the catheter. Thus, according to Applicants' invention, the diameter of the stent, or at least a portion of the stent, is expanded when it is mounted on the catheter, rather than being reduced or crimped. Penner et al. do not teach or suggest a method of mounting a stent on a delivery catheter where the stent's diameter is expanded during the mounting process.

Accordingly, Applicants respectfully request that the rejection of claims 20, 21, and 24, under 35 U.S.C. § 102(b) be withdrawn.

Claim rejections under 35 U.S.C. § 103

The Examiner rejected claims 4, 5, 22 and 23 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,725,519 (Penner et al.) in view of U.S. Patent No. 5,693,066 (Rupp et al.).

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Claims 4 and 5 have been canceled without prejudice above. Accordingly, this rejection of these claims is rendered moot.

Applicants respectfully traverse this rejection of claims 22 and 23.

As discussed above and hereby incorporated herein by reference, Penner et al. describe a particular method of "crimping" a stent on a balloon catheter. Rupp et al. describe another method of crimping a stent over a balloon catheter. In Rupp et al., a stent storage and delivery device is disclosed wherein the stent is installed first over a mandrel. The stent may be expanded slightly as it is slipped over the mandrel. The stent is then slid over the mandrel and then onto the balloon catheter. Then the stent is crimped against the balloon to assume its delivery configuration. Thus, prior to being mounted on the delivery catheter, the stent of Rupp et al. has a diameter at all times and all locations which is greater than its delivery diameter.

Thus the teachings of Rupp et al. do not describe the present invention, in which the stent is loaded onto a delivery catheter while in a radially contracted position having a diameter less than the diameter of the stent when loaded on the catheter in its delivery configuration. Claims 22 and 23 are directed to methods in which the diameter of the radially contracted position is smaller than the diameter of the delivery catheter by at least 5% and 25%, respectively.

Neither Penner et al. nor Rupp et al., alone or in combination, teach a method of mounting a stent on a delivery catheter where the stent's diameter is expanded during the mounting process.

Accordingly, Applicants respectfully request that the rejection of claims 22 and 23 under 35 U.S.C. § 103(a) be withdrawn.

Allowable Subject Matter

Claims 10 to 19, 25 to 33, and 37 to 40 were deemed allowable.

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New Claims

New claims 41 to 46 have been added. New independent claim 41 recites a method of loading a stent having a post-compression diameter onto a delivery catheter having a diameter greater than the post-compression diameter. Dependent claims 42 to 46 recite unique combinations of elements that add further limitations to claim 41.

Applicants assert that the prior art does not teach or suggest claims 41 to 46.

In view of Applicants' remarks, all of the claims are believed to be in condition for allowance. Reconsideration, withdrawal of the rejections, and passage of the case to issue is respectfully requested.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: 1/30/03

Rv

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them causing stent 10 to slide onto the outside of element 20, or again by means of a movement involving both element 20 and stent 10 together.

In particular, the action of "feeding" of stent 10 onto element 20 is preferably facilitated by means of a coupling insert 4 which may, for example, consist of a sort of sheath which comprises a portion having a conical shape or the shape of a truncated cone and is made of a material having a low coefficient of friction (for example, polytetrafluoroethylene or similar materials) and a reasonable degree of flexibility, also in relation to its thickness.

Coupling insert 4 is set on the end of element 20 starting from which the sliding movement of stent 10 onto element 20 is performed.

It will moreover be appreciated that, in the case where element 20 is made up of the balloon of a catheter, coupling insert 4 (which is generally eliminated and removed once the desired coupling of stent 10 and of element 20 has been achieved) has a shape that adapts to the approximately conical, or anyway tapered, shape which the aforementioned end of the balloon normally already has in any case (see, for example the right-hand part of Figure 1).

Figures 5 and 6 show the action of coupling between stent 10 and element 20 consists essentially in two possible effects which can be exploited both as alternatives and in combination, according to the specific application requirements.

In particular, Figure 5 refers to a situation in which while stent 10 is being fitted onto element 20 it is not subjected to an action of containment in a radial direction.

Since, as has already been seen, the internal diameter d2 of stent 10 is at least marginally smaller than the external diameter d1 of element 20, in these conditions the coupling movement is performed (assuming, from a purely conceptual standpoint, that element 20 is radially incompressible) as a result of a slight radial expansion of stent 10 which brings the internal diameter of the latter from the value d2 to the value d1.

Figure 6 illustrates, during the aforesaid movement of insertion, that stent 10 undergoes an action of radial containment, for instance by setting on it sheath 5



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5

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